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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/795,933

03/08/2004

Jan Zavada

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2689

24988

7590

03/04/2008

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EXAMINER

SHIN, DANA H

ART UNIT

PAPER NUMBER

1635

NOTIFICATION DATE

DELIVERY MODE

03/04/2008

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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<b>Office Action Summary</b>	<b>Application No.</b> 10/795,933	<b>Applicant(s)</b> ZAVADA ET AL.	
	<b>Examiner</b> DANA SHIN	<b>Art Unit</b> 1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 15 January 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 31-35 and 39-55 is/are pending in the application.
- 4a) Of the above claim(s) 41-52 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 31-35, 39, 40 and 53-55 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

As a result of a pre-appeal conference held on February 13, 2008, further prosecution/reconsideration of the instant case has been deemed proper. Accordingly, this Office action contains new grounds of rejection.

#### ***Status of Application/Amendment/Claims***

This Office action is in response to the communications filed on January 15, 2008.

Currently, claims 31-35 and 39-55 are pending. Claims 41-52 have previously been withdrawn as being drawn to a non-elected invention. Accordingly, claims 31-35, 39-40, and 53-55 are under examination on the merits in the instant case.

The following rejections are either newly applied or are reiterated and are the only rejections and/or objections presently applied to the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

#### ***Priority***

Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-

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filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed application, Application No. 08/260,190 (now US Patent 6,774,117), fails to provide adequate support in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application.

In the instant case, claims 31-35 and 53-55 are drawn to an MN antisense construct comprising a vector containing a transcribable MN antisense oligonucleotide operably linked to an expression control sequence, wherein said MN antisense construct shows antisense activity in cells *in vitro* and said MN antisense oligonucleotide is between 19 and 29 nucleotides in length. Claims 39-40 are drawn to methods of blocking MN gene expression *in vivo* in a human and treating neoplastic diseases in a human by administering said MN antisense construct.

It is found that the disclosure of US Patent 6,774,117 does not provide adequate written description or support for an expression vector containing an MN antisense oligonucleotide which is operably linked to an expression control sequence, wherein said expression vector is capable of inhibiting MN expression in a human or treating a neoplastic disease. Furthermore, nowhere in the disclosure of US Patent 6,774,117 is there a statement that the instantly claimed MN antisense vector carrying a 19-mer or 29-mer antisense oligonucleotide is envisioned by the inventors. The naked antisense oligonucleotides (see column 36 and Example 10) and the vector comprising a full-length antisense cDNA (see column 26) described in the disclosure of US Patent 6,774,117 do not whatsoever represent adequate support and description for the instantly claimed expression vector structure.

In other words, the disclosure of US Patent 6,774,117 provides adequate support for individual elements or parts of the claimed antisense construct in a different context (e.g., naked antisense oligonucleotides, a construct comprising full length antisense MN cDNA) than what is actually being claimed in the instant case. Note that the purpose of the written description requirement set forth in the first paragraph of 35 U.S.C. 112 is “to ensure that the inventor had possession, as of the filing date of the application relied on, of the specific subject matter later claimed by him.” *In re Edwards*, 568 F.2d 1349, 1351-52, 196 USPQ 465, 467 (CCPA 1978). (emphasis added).

Since the actual structure of the claimed antisense construct *per se* having all of the structural limitations set forth in the claims is neither described nor suggested in the disclosure of US Patent 6,774,117, the benefit of an earlier filing date is denied in the instant case. Accordingly, the instant filing date of March 8, 2004 will be the effective filing date for the instantly claimed invention in claims 31-35, 39-40, and 53-55.

If applicant believes US Patent 6,774,117 provides adequate written description and support for the instantly claimed subject matter of claims 31-35, 39-40, and 53-55 in the manner provided by the first paragraph of 35 U.S.C. 112, applicant is advised to point out the particulars in response to this Office action. Absent evidence to the contrary, March 8, 2004 will remain as the effective filing date for claims 31-35, 39-40, and 53-55.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 31-35, 39-40, and 53-55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zavada et al. (US 6,051,226) in view of Benedetti et al. (*Molecular and Cellular Biology*, 1991, 11:5435-5445, citation of record).

The claims are drawn to a vector containing a transcribable MN antisense oligonucleotide operably linked to an expression control sequence, wherein said vector shows antisense activity in cells *in vitro* and said MN antisense oligonucleotide is SEQ ID NO:3, 4, or 7, and methods of blocking MN gene expression *in vivo* in a human and treating neoplastic diseases in a human by administering said vector.

Zavada et al. teach MN antisense oligonucleotides of SEQ ID NOs:3 and 4 inhibit MN expression in HeLa cells. See Example 11. They teach that the two antisense oligonucleotides are representative of many antisense oligonucleotide sequences that can function to inhibit MN gene expression and that one of ordinary skill in the art would be able to determine appropriate

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antisense oligonucleotide sequences from the MN cDNA sequence. See column 28. They teach that such antisense oligonucleotides are useful for cancer therapy. See column 27. They also teach an MN-specific antisense oligonucleotide sequence of SEQ ID NO:7. See column 13. Zavada et al. do not teach making a vector-based construct carrying an MN-specific antisense oligonucleotide that is 19-29 nucleotides in length.

Benedetti et al. teach a vector-based construct carrying and expressing a 20-mer antisense oligonucleotide that is operably linked an inducible promoter, wherein the construct inhibits target gene expression in HeLa cells. They teach the method of constructing the vector-based construct. See pages 5436-5437. They also describe other expression vector systems carrying antisense RNAs, which were used by other researchers. See page 5442. They teach that one of ordinary skill in the art can regulate the level of antisense RNA expression by employing the vector-based antisense construct system containing an inducible promoter and that such antisense expression system is useful both *in vitro* and *in vivo*. See pages 5442-5443.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make and use an expression vector-based antisense construct to express MN antisense oligonucleotides in human tumor cells both *in vitro* and *in vivo* by following the methodology used in Benedetti et al.

One of ordinary skill in the art would have been motivated to insert any one of SEQ ID NOs:3, 4, and 7 of the instant application, all of which have the potential for antisense activity against the MN gene, into the expression vector containing an inducible promoter of Benedetti et al., in order to regulate the temporal expression of the MN antisense oligonucleotide in human tumor cells both *in vitro* and *in vivo*. One of ordinary skill in the art trying to construct the

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claimed vector-based MN antisense expression construct would have predicted to succeed in producing the claimed construct and using it in human tumor cells *in vitro*, because Benedetti et al. provided adequate guidelines for the antisense expression vector cloning technology and the transfection methodology. Furthermore, one of ordinary skill in the art would have had a reasonable expectation of success in applying the claimed MN antisense construct in an *in vivo* cancer therapeutic regimen as claimed in the instant case, because Zavada et al. expressly taught that any one of the MN antisense oligonucleotides designed by a skilled artisan can be used in cancer therapy.

Alternatively, instead of using the inducible promoter-containing expression vector of Benedetti et al., one of ordinary skill in the art would have been motivated to utilize the vector used in Zavada et al., which contained a full-length antisense MN cDNA, as the expression vector to carry and express the MN antisense oligonucleotide of SEQ ID NO:3, 4, or 7, because the vector containing the MN promoter of Zavada et al. was shown to be effective not only in expressing the full-length antisense MN cDNA in cells *in vitro* but also in inhibiting MN expression in the cells. Since both the cloning technology and transfection methods comprising an expression vector containing an antisense oligonucleotide of 20 nucleotides in length were known in the art as taught by Benedetti et al., one of ordinary skill in the art would have had a reasonable expectation of success in making the claimed construct and using it in the methods as claimed in the instant case.

Since all of the necessary components and method steps required to arrive at the instantly claimed invention were known and available in the art as of the earliest filing date granted in the instant case, and since both knowledge and skills required to arrive at the claimed invention were



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within the technical grasp of one of ordinary skill in the art at the time of the invention, the claimed invention taken as a whole would have been *prima facie* obvious at the time of the instant filing date.

### ***Conclusion***

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DANA SHIN whose telephone number is (571)272-8008. The examiner can normally be reached on Monday through Friday, from 8am-4:30pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Douglas Schultz can be reached on 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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